DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 24, 2015

THD SpA
% Mr. Maurizio Pantaleoni
Isemed srl
Via Argentina Altobelli Bonetti, 3
40026, Imola BO
Italy

Re: K141657
Trade/Device Name: THD Revolution
Regulation Number: 21 CFR 892.1540
Regulation Name: Nonfetal ultrasonic monitor
Regulatory Class: Class II
Product Code: JAF
Dated: December 12, 2014
Received: December 12, 2014

Dear Mr. Pantaleoni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141657

Device Name
THD Revolution

Indications for Use *(Describe)*
The THD Revolution is intended to be used for the surgical treatment of hemorrhoidal disease. This treatment is based on the Doppler-guided Transanal Haemorrhoidal Dearterialization technique.
The technique consists of locating and ligating the terminal branches of the superior haemorrhoidal artery using the THD Revolution device and the compatible single-use THD kits.
THD Revolution and its accessories may exclusively be used by specialist physicians for ligation of the terminal branches of the superior haemorroidal artery in hospital facilities (or suitable aseptic outpatient facilities). Furthermore, by using the optic fiber accessory of the THD Revolution, it can be used in modality "Light Source", to support the different THD diagnostic devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for the THD Revolution

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

2.1. General Information

Submitter: THD S.p.A.
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Summary Preparation Date: December 11, 2014

2.2. Names

Device Name: THD Revolution
Classification Name: Nonfetal Ultrasonic monitor
Product Code: JAF
Regulation number: 892.1540

2.3. Predicate Devices

The THD Revolution is equivalent to the following devices:

Applicant	*Device name*	*510(k) Number*
G.F. S.R.L.	THD	K070815
THD SpA	THD Slide	K081429
THD SpA	THD Slide One	K090009

2.4. Device Description

Identically to the predicate devices K090009, K081429 e K070815, the THD Revolution is a 8 MHz continuous wave (CW) Doppler detector with a loudspeaker and a light source.
Further, as the predicate device, the THD Revolution doppler is used with dedicated accessories (optical fiber and pneumatic foot pedal) and a dedicated kit containing a proctoscope, needle holder, knot tightener, sutures, doppler probe and Surgy proctoscope in order to allow the surgical operation through the Transanal Hemorroidal Dearterialization (THD) technique. In particular, the THD Revolution is compatible with any of the following kits:

- THD Slide,
- THD Slide One,
- THD Easy,
- THD Easy one,
- THD Basic,
- THD Basic plus.

The THD Slide and THD Slide one kits have been previously cleared (510(k) number: K081429 and K090009 respectively) and there have been no changes to the kits since their clearance. All the other kits consist of different combinations of one or more components characterizing the cleared THD Slide kit (K081429), THD Slide One kit (K090009), THD kit (K070815) or the Surgy proctoscope (K091490).

Furthermore, the THD Revolution can be used in “Light Source” mode to allow the doctor to perform inspections by using the optic fiber accessory.

2.5. Indications for Use

The THD Revolution is intended to be used for the surgical treatment of hemorrhoidal disease. This treatment is based on the Doppler-guided Transanal Haemorrhoidal Dearterialization technique.
The technique consists of locating and ligating the terminal branches of the superior haemorrhoidal artery using the THD Revolution device and the compatible single-use THD kits.
THD Revolution and its accessories may exclusively be used by specialist physicians for ligation of the terminal branches of the superior haemorroidal artery in hospital facilities (or suitable aseptic outpatient facilities). Furthermore, by using the optic fiber accessory of the THD Revolution, it can be used in modality "Light Source", to support the different THD diagnostic devices.

Concerning the surgical treatment of the hemorrhoids through the THD technique, the THD Revolution is equivalent to the predicate devices K090009, K081429 and K070815.

The "Light Source" mode represents an additional function of the THD Revolution allowing illumination and observation. In such modality the THD Revolution supports the THD family of diagnostic devices already cleared in K091490.

2.6. Technological characteristics

Identically to the predicate devices K090009, K081429 and K070815, the THD Revolution consists of a doppler device and the following accessories:

- THD Optical fiber
- Pneumatic foot pedal
- Back-up doppler probe
- Kit

- **Doppler device**

The THD Revolution doppler represents an evolution of the original Doppler called THD Evolution which was cleared together with its specific kit under the 510K numbers: K07815 (THD kit), K081429 (THD Slide kit) and K090009 (THD Slide one kit).

From a technical and technological point of view, the THD Revolution Doppler has some new features compared to the predicate devices:

- Design: The THD Revolution consists of a double thermoplastic shell containing an 8 MHz continuous wave (CW) Doppler detector with loudspeaker and a light source.

These characteristics are identical to the predicate devices K07815, K081429 and K090009.

- General Wiring**:** Schematically the THD Revolution consists of: **1)** a power input module; **2)** two power management suppliers (one supplying the LED and the other one supplying all the other parts of the device) working within the range 115-230V and compliant with IEC 60601-1:2005; **3)** a Doppler module controlling the Doppler functions (ultrasound signal); **4)** a main board consisting of a DSP microprocessor which manages all the utilities (Doppler module, loudspeaker, Led on/off and Led light intensity), **5)** a Push buttons board with a display representing the user interface; **6)** a LED module consisting of a 50W LED emitter, a thermal switch, a fan system and a sensor detecting the optical fiber; **7)** a loudspeaker with the electronic circuitry installed on the Doppler module.

  The general wiring of the predicate devices K07815, K081429 and K090009 is identically to the THD Revolution with regards to: **1)** the power input module; **2)** the Doppler module; **3)** the Push buttons board and **4)** the loudspeaker.

  The predicate devices K07815, K081429 and K090009 differ from the THD Revolution with regards to the following aspects: **1)** the predicates devices have a voltage selector for the manual regulation of the electric power (115V or 230V) and consequently they are provided with a power supply transformer instead of the two power managements boards characterizing the THD Revolution. *Identically to the THD Revolution the transformer guarantees the compliance with IEC 60601-1:2005*; **2)** the predicate devices do not have a main board with DSP microprocessor since all the signals are processed through analogic circuitry. Therefore, the

predicate devices have a power supply board, which supplies all the utilities (Doppler module, loudspeaker and light); **3)** the light source of the predicate devices is an analogic lamp and not a LED.

- Power supply: The THD Revolution is characterized by a power supply of 115-230Vac +/-10% (Voltage); 50-60Hz (Frequency) and 100VA (Absorption).
  These characteristics are identical to the predicate devices K07815, K081429 and K090009.
- Light source: Both the THD Revolution and the predicate device have an internal light source to illuminate the surgical field during the procedure.
  However, the THD Revolution's light source is a LED (50W) while the predicate devices light source is a tungsten halogen lamp (50W). The LED technology improves the illumination of the surgical area and allows to minimize the maintenance operations that by contrary are required to change the lamp of the predicate devices if damaged. Furthermore, the THD Revolution allows to control the light of the LED either by manually regulating its intensity or by automatically turning the light off if the optic fiber is not connected correctly to the device. Such features satisfy higher standards compared to the predicate devices.
  Therefore, the THD revolution's new features offer better control and higher safety compared to the predicate devices without raising new questions.
- Acoustic output level: The THD Revolution's acoustic output is characterized by the following values: 347 mW/cm^2 (Max Ispta3); 0,347 W/cm^2 (Max Isppa3) and 0,032 (Max MI).
  These parameters are the same as the predicate device K090009.
- Digital Signal Processor (DSP): The THD Revolution is equipped with DSP technology that improves the acoustic signal quality reducing the noise and thus guaranteeing a clearer signal compared to the predicate devices K07815, K081429 and K090009 that by contrary do not have DSP.
  Specific performance test demonstrates that the acoustic signal of the THD Revolution is at least as good as the predicate devices, confirming the substantial equivalence.
  The THD Revolution' acoustic signal is equivalent to the predicate devices in term of audibility and its even clearer thanks to DSP technology.
- Adjustable parameters: The THD Revolution allows the regulation of the light intensity within the range 40-100% (step 10%) and of the volume of the loudspeaker
  The predicate devices K07815, K081429 and K090009 allow the regulation of the volume of the loudspeaker but not of the light intensity.
  Identically to the predicate devices K07815, K081429 and K090009, the THD Revolution allows the regulation of the volume of the loudspeaker. Also, the THD Revolution allows the regulation of the light intensity guaranteeing higher performance standards compared to the predicate devices.

- **Doppler probe**

THD Revolution is supplied with two identical Doppler probes called "THD Slide Doppler probe".

One THD Slide Doppler probe is included into each compatible kit and represents the probe to be used for the surgical procedure. Such probe can be sterile and disposable as well as non-sterile and reusable (5 treatments).
The other THD Slide Doppler probe represents the back-up Doppler probe to be used as substitute in the event the probe provided with any of the THD Revolution's kits malfunctions. The back-up Doppler probe is supplied sterile and disposable.

The THD Slide Doppler probe has been already cleared in K081429 and K090009 and no changes have been made since its clearance.

- **Optical fiber and pneumatic pedal**

The optical fiber and the pneumatic foot pedal provided with the THD Revolution are exactly the same as those of the predicate devices (K07815, K081429 and K090009).

- **Kit**

The THD Revolution Doppler is compatible with any of the following kits:

1. THD Slide,
2. THD Slide One,
3. THD Easy,
4. THD Easy one,
5. THD Basic,
6. THD Basic plus.
7.

The THD Slide and THD Slide one kits have been previously cleared (510(k) number: K081429 and K090009 respectively) and there have been no changes to the kits since their clearance. All the other kits consist of different combinations of one or more components characterizing the cleared THD Slide kit (K081429), THD Slide One kit (K090009), THD kit (K070815) or the Surgy proctoscope (K091490).

2.7. Material in contact with patients

Identically to the predicate devices K07815, K081429 and K090009, the THD Revolution's components that can come in contact with the patient are the THD slide Doppler probe (made of Makrolon 2458), the proctoscope (made of Makrolon 2458), the needle holder (made of AISI 410 steel) and sutures (K041515) characterizing the THD Slide kit, THD Slide one Kit, THD Easy kit, THD Easy one Kit, THD Basic kit and THD Basic Plus Kit. All the three components are exactly the same as the predicate devices (K07815, K081429 and K090009) with regards to technology and materials they are manufactured with.
Further, the THD Basic and Basic Plus kits have also the Surgy proctoscope that comes in contact with the patient. Such device is made of biocompatible Makrolon 2458 as the proctoscope previously mentioned. The Surgy proctoscope is alreadycleared in K091490 and no changes have been made since its clearance.

2.8 Performance data

1. Identically to the predicate devices K07815, K081429 and K090009, the THD Revolution has been manufactured according to the following standards:
   - IEC 60601-1
   - IEC 60601-2-37
   - IEC 60601-1-2

2. Acoustic signal:
   The THD Revolution has been provided with DSP technology in order to improve the quality and control of the acoustic signal reducing the noise. It means that the acoustic signal is processed through the DSP microprocessor and then emitted through the loudspeaker. The emission of the acoustic signal through the loudspeaker of the THD Revolution is exactly the same as the predicate devices' Doppler (THD Evolution) cleared in K07815, K081429 and K090009.
   - A performance test was conducted to verify the acoustic output level considering the THD Evolution Doppler and the THD Slide Doppler probe cleared in K081429 and K090009 which is exactly the same probe provided with the THD Revolution. Therefore, given that the THD Revolution's Doppler probe is exactly the same as the predicate devices K090009 and the acoustic signal broadcasting system of the THD Revolution is exactly the same as the THD Evolution Doppler cleared in K07815, K081429 and K090009, the test conducted on the THD Evolution is valid for the THD Revolution as well.
     The acoustic output levels resulted from the test are: 347 mW/cm^2 (Max Ispta3); 0,347 W/cm^2 (Max Isppa3) and 0,032 (Max MI).
   - Given that the DSP technology characterizes the THD Revolution but not the predicate devices's THD Evolution Doppler (K081429, K070815 and K090009), a specific test was conducted comparing the acoustic signal emitted by the THD Revolution Doppler with the output signal characterizing the Doppler of the predicate devices (THD Evolution Doppler cleared in K081429, K070815 and K090009). The obtained results demonstrate the equivalence of the signal underling that the THD revolution's acoustic signal is at least as good as the predicate devices, and better yet, it's clearer thanks to the DSP that sharply reduces the background noise.

3. Light source: luminous efficacy and photobiological safety

   The THD Revolution light source is represented by a LED while the light source of the predicate devices K081429, K070815 and K090009 is an halogen lamp. Both the light source have the same watt (50 W).

   - The LED of the THD Revolution has been tested according to IEC 62471 (1st Edition) to evaluate the photobiological safety. The device under test was a THD

Revolution prototype representative of the standard THD SpA production. The device was connected to the dedicated optical fiber. The results demonstrate the compliance with the standard IEC 62471 and the LED source has been classified as "Risk group: Exempt".

- In order to test the luminous efficacy of the THD Revolution's LED compared to the hanalogic lamp of the predicate devices a specific test was conducted.
  The test was performed using the THD Revolution and the predicate device THD Evolution (cleared in K081429, K070815 and K090009). Both the devices were connected to the optical fiber and the luminous efficacy was measured by means of a dedicated digital illuminance meter. The obtained results underline greater luminous efficacy for the THD Revoution's LED (10300 lux) than for the predicate device's halogen lamp (1580 Lux), demonstrating higher illumination in case of the THD Revolution.

4. Performance data-Clinical:
   Specific clinical studies have been conducted in order to demonstrate that the THD Revolution is effectiveness not only for the surgery of haemorrhoids of second and third degree like the predicate devices K081429, K070815 and K090009 but also for grade IV haemorrhoids characterized by prolapse that cannot be manually reduced.

   - Transanal dearterialization with targeted mucopexy is effective for advanced haemorroids. Giorndano P, Tomasi I, Pascariello A, Mills E and Elahi S. Colorectal Dis. 2014 May;16(5):373-6.

     Methods: 31 patients with IV grade haemorroids characterized by constant prolapse were operated using the THD Revolution and consequently the THD technique (transanal haemorroidal dearterialization).
     Results: the study demonstrates that the THD device is effective in the treatment of grade IV hemorrhoids revealing no intra-operative complications and only one case of recurrence that was treated by surgical removal.
     Conclusions: the THD device allows accurate transfixaction and ligation of the artery and further it guarantees the area of prominent prolapsed to be targeted by dividing the procedure into two phases, dearterialization and plication.

   - Transanal haemorrhoidal dearterialization as alternative surgical treatment to hemorrhoidal disease:initial report. Morrett R.S. Crujano General. Vol 34 Num 2; 2012.

     Methods: 250 patients with grade II-III and IV (21 patients) haemorroids were operated using the THD technique (transanal haemorroidal dearterialization) consisting in ligating the branches of the superior rectal artery and performing the mucosapexis to correct the prolapse
     Results: there were no intra-operative complications and the post operative pain was very low (73% of patients reported 0-1 according to AVS). The satisfactoriness grade (8-10 according to AVS) was reported to be high (8-10 according to AVS).

Conclusion:
The THD Technique resulted effective in the treatment of haemorroids of second, third and forth degree (characterized by constant prolapsed). The THD technique resulted safe and effective and with low incidence of complications.